

## INTERNATIONAL COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner  
 US Department of Commerce  
 United States Patent and Trademark  
 Office, PCT  
 2011 South Clark Place Room  
 CP2/5C24  
 Arlington, VA 22202  
 ETATS-UNIS D'AMERIQUE  
 in its capacity as elected Office

<b>Date of mailing (day/month/year)</b> 05 June 2001 (05.06.01)	
<b>International application No.</b> PCT/CA00/01011	<b>Applicant's or agent's file reference</b> 78162-20
<b>International filing date (day/month/year)</b> 30 August 2000 (30.08.00)	<b>Priority date (day/month/year)</b> 30 August 1999 (30.08.99)
<b>Applicant</b> WRIGHT, Jeffrey, L., C. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

15 March 2001 (15.03.01)

☐ in a notice effecting later election filed with the International Bureau on:
2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No.: (41-22) 740.14.35	<b>Authorized officer</b> Charlotte ENGER Telephone No.: (41-22) 338.83.38
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# TENT COOPERATION TREATY

# PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>78162-20</b>	<b>FOR FURTHER ACTION</b>		see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. <b>PCT/CA 00/ 01011</b>	International filing date (day/month/year) <b>30/08/2000</b>	(Earliest) Priority Date (day/month/year) <b>30/08/1999</b>	
Applicant <b>OCEAN NUTRITION CANADA LTD. et al.</b>			

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.  
☒ It is also accompanied by a copy of each prior art document cited in this report.

### 1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

## INTERNATIONAL SEARCH REPORT

Intern. Application No  
PCT/CA 00/01011

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A23L1/30 A61K31/575 C11C3/00 C07J9/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A23L A61K C11C C07J

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, FSTA, BIOSIS

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	EP 0 897 970 A (UNILEVER PLC ;UNILEVER NV (NL)) 24 February 1999 (1999-02-24) claims 1,3-7; example 1  column 1, line 1-19 column 2, line 41 -column 3, line 43 --- -/--	1-3,7, 13,26-31 8-12, 32-37

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*G\* document member of the same patent family

Date of the actual completion of the international search

10 January 2001

Date of mailing of the international search report

18 -01- 2001

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
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Authorized officer

Tallgren, A

## INTERNATIONAL SEARCH REPORT

Intern. Application No.

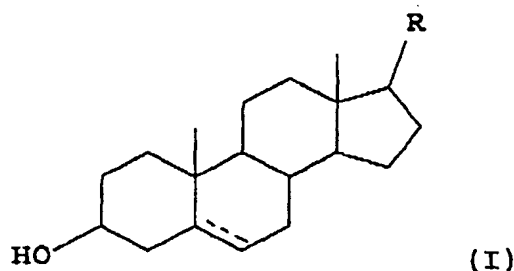
PCT/CA 00/01011

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	SHIMADA ET AL: "Enzymatic Synthesis of Steryl Esters of Polyunsaturated Fatty Acids" JOURNAL OF THE AMERICAN OIL CHEMISTS' SOCIETY, US, AMERICAN OIL CHEMISTS' SOCIETY. CHAMPAIGN, vol. 76, no. 6, June 1999 (1999-06), pages 713-716, XP002132268 ISSN: 0003-021X	1-7
A	page 713, paragraph 3  page 714, paragraph 2 page 715, paragraph 6; table 3	1-13, 26-28
X	US 4 588 717 A (MITCHELL DAVID C) 13 May 1986 (1986-05-13) claims 1-4, 7, 9; examples 1-4 column 3, line 26-36 column 5, line 43 - column 6, line 38	1-4, 7-9, 13, 26-28
P, X	EP 1 004 594 A (HOFFMANN LA ROCHE) 31 May 2000 (2000-05-31) claims 1-7, 9, 10; examples 1, 7, 9, 10; table 2 page 2, line 3-15, 21-24 page 3, line 1-8 page 6, line 1-31, 39-46	1-9, 12, 13, 26-30
A		10, 11, 31-37
P, X	EP 0 982 315 A (MCNEIL PPC INC) 1 March 2000 (2000-03-01)  claims 1, 2, 5-7, 9, 21; examples 6-9 page 2, line 45 - page 3, line 10, 30-39 page 5, line 15-23 page 6, line 16-50	1-4, 6, 7, 9, 12, 26-28

CLAIMS:

1. Use of an ester between a sterol and eicosapentaenoic acid 20:5 $\omega$ 3 (EPA), docosahexaenoic acid 22:6 $\omega$ 3 (DHA) or a mixture of EPA and DHA for lowering  
5 cholesterol and triglyceride levels in the bloodstream of a subject in need thereof.
2. The use according to claim 1, wherein the sterol is a phytosterol.
3. The use according to claim 1 or 2, wherein the  
10 sterol has the formula (I):



- 15 wherein R is a (C<sub>1</sub>-C<sub>10</sub>)alkyl, substituted (C<sub>1</sub>-C<sub>10</sub>)alkyl, (C<sub>2</sub>-C<sub>10</sub>)alkenyl or substituted (C<sub>2</sub>-C<sub>10</sub>)alkenyl group and the dashed line indicates that a double or single bond may exist at that location in the sterol.
4. The use according to claim 1 or 2, wherein the  
20 sterol is stigmasterol.
5. The use according to claim 1 or 2, wherein the sterol is sitosterol.
6. The use according to claim 1 or 2, wherein the sterol is fucosterol.
- 25 7. The use according to claim 1 or 2, wherein the sterol is fucostanol.

8. The use according to claim 1 or 2, wherein the sterol is  $\beta$ -sitostanol.

9. The use according to any one of claims 1 to 8, wherein a mixture of EPA and DHA is used.

5 10. The use according to any one of claims 1 to 9, wherein the EPA, DHA or mixture of EPA and DHA is derived from fish oil.

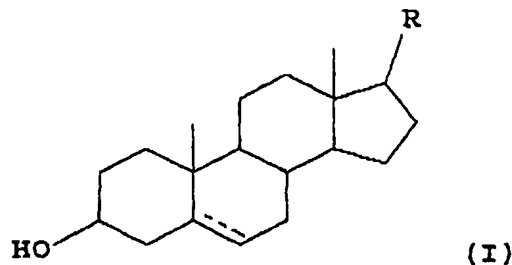
11. The use according to any one of claims 1 to 10, wherein the ester is used in the form of a nutritional  
10 supplement.

12. The use according to claim 11, wherein the nutritional supplement further comprises an edible additive.

13. Use of an ester between a sterol and  
eicosapentaenoic acid 20:5 $\omega$ 3 (EPA), docosahexaenoic acid  
15 22:6 $\omega$ 3 (DHA) or a mixture of EPA and DHA for manufacturing a nutritional supplement for lowering cholesterol and triglyceride levels in the bloodstream of a subject in need thereof.

14. The use according to claim 13, wherein the sterol  
20 is a phytosterol.

15. The use according to claim 13 or 14, wherein the sterol has the formula (I):



wherein R is a (C<sub>1</sub>-alkyl, substituted (C<sub>1</sub>-C<sub>10</sub>)alkyl, (C<sub>2</sub>-C<sub>10</sub>)alkenyl or substituted (C<sub>2</sub>-C<sub>10</sub>)alkenyl group and the dashed line indicates that a double or single bond may exist at that location in the sterol.

- 5 16. The use according to claim 13 or 14, wherein the sterol is stigmasterol.
17. The use according to claim 13 or 14, wherein the sterol is sitosterol.
18. The use according to claim 13 or 14, wherein the  
10 sterol is fucosterol.
19. The use according to claim 13 or 14, wherein the sterol is fucostanol.
20. The use according to claim 13 or 14, wherein the sterol is  $\beta$ -sitostanol.
- 15 21. The use according to any one of claims 13 to 20, wherein a mixture of EPA and DHA is used.
22. The use according to any one of claims 13 to 21, wherein the EPA, DHA or mixture of EPA and DHA is derived from fish oil.
- 20 23. The use according to any one of claims 13 to 22, wherein the nutritional supplement further comprises an edible additive.
24. A process for preparing an ester between a sterol and eicosapentaenoic acid 20:5 $\omega$ 3 (EPA), docosahexaenoic acid  
25 22:6 $\omega$ 3 (DHA) or a mixture of EPA and DHA, which comprises the step of reacting the sterol with EPA, DHA, a mixture of EPA and DHA or an ester thereof in the presence of a base.

25. The process according to claim 24 wherein the base is a metal ( $C_1$ - $C_{10}$ ) alkoxide.

26. A process according to claim 25, wherein the metal ( $C_1$ - $C_{10}$ ) alkoxide is sodium methoxide.

5 27. The process according to any one of claims 24 to 26, which further comprises the step of precipitating unreacted sterol with a suitable non-polar solvent, and filtering off the precipitated unreacted sterol to leave a filtrate.

10 28. The process according to claim 27, wherein the non-polar solvent is hexane.

29. The process according to claim 27 or 28, which further comprises the step of extracting the filtrate with a suitable immiscible solvent to remove unreacted EPA, DHA or  
15 ester thereof, from the filtrate.

30. A process according to claim 29, wherein the immiscible solvent is methanol.

31. A process according to any one of claims 24 to 30, wherein the ester of EPA, DHA or mixture thereof is a  
20 triglyceride ester.

32. A process according to any one of claims 24 to 30, wherein the ester of EPA, DHA or mixture thereof is an ethyl ester.

33. A process according to any one of claims 24 to 30,  
25 wherein the EPA, DHA or mixture thereof is derived from fish oil.

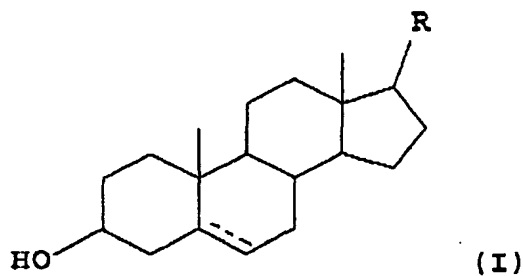
34. A method comprising: administering a blood serum cholesterol and triglyceride lowering effective amount of an ester formed between a sterol and eicosapentaenoic acid



20:5 $\omega$ 3 (EPA), docosahexaenoic acid 22:6 $\omega$ 3 (DHA), or a mixture of EPA and DHA, to a subject in need thereof.

35. The method according to claim 34, wherein the sterol is a phytosterol.

5 36. The method according to claim 34 or 35, wherein the sterol has the formula (I):



10 wherein R is a (C<sub>1</sub>-C<sub>10</sub>)alkyl, substituted (C<sub>1</sub>-C<sub>10</sub>)alkyl, (C<sub>2</sub>-C<sub>10</sub>)alkenyl or substituted (C<sub>2</sub>-C<sub>10</sub>)alkenyl group and the dashed line indicates that a double or single bond may exist at that location in the sterol.

15 37. The method according to claim 34 or 35, wherein the sterol is stigmasterol.

38. The method according to claim 34 or 35, wherein the sterol is sitosterol.

20 39. The method according to claim 34 or 35, wherein the sterol is fucosterol.

40. The method according to claim 34 or 35, wherein the sterol is fucostanol.

41. The method according to claim 34 or 35, wherein the sterol is  $\beta$ -sitostanol.

25 42. The method according to any one of claims 34 to 41, wherein a mixture of EPA and DHA forms the ester with the sterol.

43. The method according to any one of claims 34 to 42, wherein the EPA, DHA or mixture thereof is derived from fish oil.

44. The method according to any one of claims 34 to 43, wherein the ester is administered in the form of a nutritional supplement.

45. The method according to claim 44, wherein the nutritional supplement further comprises an edible additive.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

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International application No. PCT/CA00/01011

examples 9 and 10 ; claims 1 - 10). The first priority document of D8 was filed before the priority date of the present invention and discloses the use of sterol esters of DHA and EPA for both the lowering of cholesterol and triglyceride levels in bloodstream. The subject-matter of claims 1 - 9, 12 - 22, 25 - 31, 36, 37 is anticipated by the disclosure of D8.

D9 relates to the preparation of stanol esters. Serum cholesterol levels will be reduced (p. 5, l. 40 - p. 6, l. 17; p. 7, l. 7 - 10). The subject-matter of claims 1 - 4, 6, 7, 12, 27, 28 is anticipated.

**Ad VIII.:**

1. The subject-matter of claims 2 and 7 seems to be redundant (Article 6 PCT).

## PCT

WIPO

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 78162-20/pw	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CA00/01011	International filing date (day/month/year) 30/08/2000	Priority date (day/month/year) 30/08/1999
International Patent Classification (IPC) or national classification and IPC A23L1/30		
Applicant OCEAN NUTRITION CANADA LTD. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 8 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☒ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand  15/03/2001	Date of completion of this report  22.11.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Krajewski, D  Telephone No. +49 89 2399 8472 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/CA00/01011

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):  
**Description, pages:**

1-27 as originally filed

**Claims, No.:**

1-45 with telefax of 01/11/2001

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).  
☐ the language of publication of the international application (under Rule 48.3(b)).  
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority in written form.  
☐ furnished subsequently to this Authority in computer readable form.  
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.  
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/CA00/01011

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

**see separate sheet**

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 14 - 26.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes:	Claims 14 - 26
	No:	Claims 1 - 13, 27, 28, 29 - 37
Inventive step (IS)	Yes:	Claims
	No:	Claims 14 - 26
Industrial applicability (IA)	Yes:	Claims 1 - 13, 27 - 37

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/CA00/01011

No: Claims

2. Citations and explanations  
**see separate sheet**

**VI. Certain documents cited**

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

**see separate sheet**

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:  
**see separate sheet**

**Ad I.:**

1. The applicant has filed an amended set of claims. Contrary to the invitation in the written opinion to specifically indicate which amendments have been made and where a basis may be found for these amendments in the application as originally filed (Rule 66.8(a) PCT) he has failed to comply with this invitation. This will result in the amendments not being examined as indicated in the written opinion. The IPER is thus based on the application as originally filed.

**Ad III.:**

1. Claims 14 - 26 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

**Ad V.:**

1. Reference is made to the following documents:  
D1: EP-A-0 897 970  
D2: SHIMADA ET AL: 'Enzymatic Synthesis of Steryl Esters of Polyunsaturated Fatty Acids' JOURNAL OF THE AMERICAN OIL CHEMISTS' SOCIETY, US, AMERICAN OIL CHEMISTS' SOCIETY. CHAMPAIGN, vol. 76, no. 6, June 1999 (1999-06), pages 713-716, XP002132268 ISSN: 0003- 021X  
D3: US-A-4 588 717  
D4: US 5502045 A  
D5: US 5593691 A  
D6: WO 9806405 A  
D7: Römpp Lexikon Lebensmittelchemie, Thieme, Stuttgart, 1995, p. 272, table 2

Documents D4 - D7 were not cited in the international search report.

2. The present application relates to a nutritional supplement comprising esters formed between a sterol and an omega-3 fatty acid (**claim 1** and claims 2 - 13 depending thereupon), a method of lowering cholesterol and triglyceride levels administering said mixture (claim 14 and claims 15 - 25 depending thereupon), the use of the mixtures of claims 1- 13 to lower cholesterol and triglyceride levels (claim 26), a foodstuff comprising the mixtures according to claims 1 - 13 (claim



27), the use of the supplement in the manufacture of a foodstuff (claim 28) and a process for preparing said supplement (claim 29 and claims 30 - 37 dependent thereupon).

**3. Novelty**

The subject-matter of the following claims does not meet the requirements of Article 33(2) PCT in view of the cited prior art documents. A positive International Preliminary Examination Report for the subject-matter of the dependent claims can only be established when they refer to an independent claim which meets the requirements of the PCT.

- 3.1 D2 discloses DHA esters of sterols (abstracts; p. 715). The subject-matter of claims 1 - 4, 5, 7, 9 is anticipated.
- 3.2 D3 discloses a vitamin supplement comprising an ester of  $\alpha$ -linolenic acid (18:3 (9,12,15)) and a phytosterol (claims 1, 7 and 17 and col. 3, l. 22 - 36; col. 6, l. 42 - col. 8, l. 11; especially col. 8, l. 6). The subject-matter of claims 1 - 4, 7 - 9, 13 is anticipated.
- 3.3 D4 discloses stanol fatty acid esters, in particular beta-sitostanol esters for reducing serum cholesterol level (col. 3, l. 43 - 50). The substance can be used as such or added to a food (col 5, l. 28 - 31; example 2). In example 1, rapeseed oil fatty acid ester is transesterified with  $\beta$ -sitostanol. Rapeseed oil contains large amounts of  $\alpha$ -linolenic acid (18:3 (9,12,15)), a n-3 fatty acid (see D7). The subject-matter of claims 1 - 4, 7, 12, 13, 27, 28, 29 - 31 is anticipated.
- 3.4 D5 discloses various stanol fatty acid esters as therapeutic agents in col 13 - 14 (col. 13, l. 14, 50, 51; col. 14, l. 14, 18, 59 - 61). The subject-matter of claims 1 - 8 is anticipated.
- 3.5 D6 discloses a sitostanol containing composition for use as a serum cholesterol lowering substance. The subject-matter of claims 1 - 7, 9, 12, 13, 27, 28, 29 - 31 is anticipated (claims 1 - 10).

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/CA00/01011

**4. Inventive step**

4.1 The subject-matter of independent claims 14 and 26 does not meet the requirements of Article 33(3) PCT for the following reasons: In the present application lowering of both triglyceride and serum cholesterol level was only demonstrated for phytosterol and fish oil (i.e. EPA and DHA) esters (see p. 10, l. 3 - 6, ex. 2 and 3). D6 discloses experimental results that phytosterol esters of vegetable oil fatty acids have a cholesterol but no a triglyceride level lowering effect (D6, p. 12). In view of D6 serious doubts arise if the effect claimed by the present invention is achieved over the whole broad of the claimed range. Inventive step can therefore not be acknowledged.

**5. Dependent claims**

A positive International Preliminary Examination Report for the subject-matter of the dependent claims can only be established when they refer to an independent claim which meets the requirements of the PCT.

**6. Industrial applicability**

The subject-matter of claims 1 - 13 and 27 - 37 meets the requirements of Article 33(4) PCT.

**Ad VI.:**

**1. Certain published documents (Rule 70.10)**

Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
EP-A-1004594 (D8)	31.5.2000	19.11.1999	26.11.1998 and 29.09.1999
EP-A-0982315 (D9)	01.03.2000	22.01.1999	25.08.1998 and 15.12.1998

Both documents do not constitute state of the art in the sense of Rule 64.1b) PCT.

D8 relates to a phytosterol ester of omega- 3 fatty acids effective in reducing both serum cholesterol and triglycerides (p. 3, l. 1 - 30; p. 4, table 2; p. 6, l. 1 - 11; l. 39 -46;

# INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr. n. Publication No

PCT/CA 00/01011

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0897970	A	24-02-1999	CA 2245482 A US 6106886 A	22-02-1999 22-08-2000
US 4588717	A	13-05-1986	US 4705875 A	10-11-1987
EP 1004594	A	31-05-2000	AU 6065599 A BR 9905398 A CN 1256277 A JP 2000159792 A NO 995784 A	01-06-2000 08-08-2000 14-06-2000 13-06-2000 29-05-2000
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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/CA 00/01011

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 14-25  
because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.  
☐ No protest accompanied the payment of additional search fees.